

Applicants: Jane H. Morse and James A. Knowles  
Serial No.: 09/904,380  
Filed : July 12, 2001  
Page 9

**REMARKS**

Claims 1-5, 51-53, 55-57, 59, 60, 64 and 65 were pending in the subject application. Claim 56 is indicated as allowed. By this Amendment, applicants have canceled claims 1-3, 51-53, 55, 57, 59 and 60 without disclaimer or prejudice. Claims 4, 64 and 65 have been amended to make certain formatting changes. No issue of new matter is raised by these amendments. Accordingly, claims 4, 5, 64 and 65 as amended and claim 56 will be pending in the subject application upon entry of this Amendment.

In view of the arguments below, applicants maintain that the grounds of the Examiner's rejections have been overcome, and respectfully request that these grounds of rejection be withdrawn.

**Rejection under 35 U.S.C. §112, First Paragraph**

In the March 5, 2004 Final Office Action, the Examiner stated that claims 1-5, 51, and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner stated that these claims encompass methods of detecting the broad genus of any possible mutation in the bone morphogenetic protein receptor-II (BMPRII) nucleic acid or protein, and correlating such a mutation with a pulmonary disease, giving birth to

Applicants: Jane H. Morse and James A. Knowles  
Serial No.: 09/904,380  
Filed : July 12, 2001  
Page 10

twins or triplets, or having a miscarriage. The Examiner further stated that the specification only provides a written description of the specific mutations as set forth in Figure 4, and claimed in claims 56, 64 and 65. The Examiner stated that the two relevant inquiries regarding this issue are: have a representative number of species been described by complete structure; and if not, have a representative number of species been described by sufficient relevant identifying characteristics. The Examiner then submitted that the answer is in the negative for both of these questions, and as such the genus claims cannot be justified. The Examiner also stated that while the specification discloses 19 gene-level mutations and their corresponding amino acid-level mutations, there is no description of any and every mutation which occurs in the BMPR2 gene/protein, not to mention which ones correlate with a specific disease/condition and which are neutral polymorphisms. In summary, the Examiner stated that, at the time of the invention, the inventors were clearly not in possession of the subject matter embodied in the generic method claims.

In response, applicants note for the record that they disagree with the Examiner's assertion as to their entitlement to generic claim coverage in view of 19 mutations disclosed. Applicants also note that claims 1-3, 51 and 52 have been canceled without disclaimer or prejudice and that claims 64 and 65 have been amended. Claim 4 has been amended to recite a proper claim dependency.

In view of these remarks, applicants maintain that claims 4, 5, 64 and 65 as amended are adequately supported by the

Applicants: Jane H. Morse and James A. Knowles  
Serial No.: 09/904,380  
Filed : July 12, 2001  
Page 11

disclosure and satisfy the requirements of 35 U.S.C. §112, first paragraph.

### **Claim Objection**

The Examiner further stated that claim 56 is allowable, and that claims 64 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Examiner stated that no prior art has been found teaching or suggesting detection of the specified mutations in the BMP2 gene/protein and correlating them with the predisposition to/affliction of pulmonary disease, having twins or triplets, or having a miscarriage.

In response, applicants note that claims 64 and 65 have been rewritten in independent form including the limitations of claims 2 and 3, respectively, and thus maintain that claims 64 and 65 so amended overcome the Examiner's ground of objection.

### **Summary**

In view of the amendments set forth above, applicants maintain that the grounds of the Examiner's rejections and objections set forth in the March 5, 2004 Final Office Action have been overcome. Applicants respectfully request that the Examiner reconsider and withdraw these grounds of rejection and objection, and solicit allowance of the claims now pending.

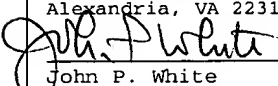
Applicants: Jane H. Morse and James A. Knowles  
Serial No.: 09/904,380  
Filed : July 12, 2001  
Page 12

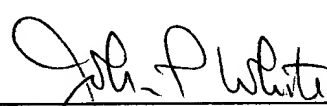
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

 5/4/04  
John P. White Date  
Reg. No. 28,678

  
John P. White, Esq.  
Registration No. 28,678  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036  
(212) 278-0400